

Remarks/Arguments

Claim 1 has been amended to identify the pressure sensitive adhesive as a silicone resin based pressure sensitive adhesive.

Claim 6 which reads on a silicone based pressure sensitive adhesive has been cancelled.

The Invention

The present invention is directed to a stable nonaqueous liquid dental whitening composition comprised of a peroxide releasing compound dispersed in an anhydrous hydrophobic pressure sensitive silicone resin based adhesive, the composition when applied to the teeth being sufficiently viscous to form an adherent, continuous layer of the peroxide containing composition on dental enamel surfaces.

The anhydrous hydrophobic liquid silicone resin based pressure sensitive adhesive of the present invention provides a stable vehicle that prevents the decomposition of the peroxide whitening agent during storage and before use. Once applied on tooth surface, the saliva on the tooth enamel surface to which the composition is applied will either dissolve or disintegrate the peroxide containing matrix resulting in a rapid decomposition of peroxide, which in turn provides the whitening effect.

As indicated at page 3, lines 9-35 specification silicone based pressure sensitive adhesives are prepared by condensing a silicone resin and an organosiloxane to produce an elastomeric, tacky material wherein the self-adhering and cohesive properties of a soft elastomer matrix characteristic of pressure sensitive polymers distinguishes the product from the hard, nonelastomeric properties of silicone resins.

Argument for Patentability

The rejection of Claims 1 to 3, 6, 8 to 10 and 13 under 35 U.S.C. 102(b) as being anticipated by '221 (WO02/34221) and '942 (WO01/01942) is respectfully traversed.

The patent courts have held that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference Cf. *Studiengesellschaft Kohle v. Dart Industries* 220 USPQ841 (Fed. Cir. 1984), *In re Spoda* 15 USPQ 2d 1655. Neither the '221 or '942 references discloses a dental whitening composition comprised of a peroxide releasing compound dispensed in a hydrophobic pressure sensitive silicone resin based adhesive.

For example, the '942 reference discloses an oral care composition comprised of an organosiloxane a volatile carrier capable of solubilizing the organosiloxane, a rheology modifier such as clays, silicas polyethylene and an oral care compound such as a peroxide compound.

There is no teaching in the '942 patent that the disclosed organosiloxane resin is a pressure sensitive silicone, such as one obtained by the condensation of a silicone resin and an organosiloxane, see applicants specification page 3, lines 9-30, wherein the silicone resin/organosiloxane ratio determines the tackiness of the pressure sensitive adhesive.

As a matter of fact, the '942 patent teaches that the organosiloxane resins "are highly crosslinked polymeric siloxane systems see page 5, lines 25-26) which are provided with a sufficient level of crosslinking such that they dry down to a rigid or hard film (page 5, lines 33-35).

The '221 patent relates to a nonvolatile composition that comprises a silicone resin, a silicon gum, a nonvolatile polysiloxane film and an oral care compound such as a peroxide compound. As in the case of the '942 patent, the '221 patent discloses that the silicone resins used in the practice of the '221 invention have a sufficient level of crosslinking "such that they dry down to a rigid or hard film (page 11, lines 4-8). "Silicone gums" are defined in the '221 patent as "high molecular weight polydiorganosiloxanes having a specific viscosity (page 12, Silicone Gums, second paragraph).

As neither the '942 patent or the '221 patent discloses a composition comprising a pressure sensitive adhesive component and since the pressure sensitive silicone resin adhesive component of the present invention differs from the compositions disclosed in these patents, both in physical properties (elastic, tacky, self adhering of the present invention, versus hard, rigid films of the cited patents) as well as chemically, (silicone resin/organosiloxane condensation product of the present invention versus highly crosslinked polymeric siloxanes induced by trifunctional and tetrafunctional silanes as disclosed in the '942, '221 patents) the '942 and '221 patents cannot by any standard of the patent law be considered to be anticipatory of the applicants invention under 35 U.S.C. 102(b).

It is further respectfully pointed out to the Examiner that in view of the fact that the teachings in both the '942 and '221 patents stipulate that the disclosed compositions form rigid or hard films upon application to tooth enamel, such teachings rebut the Examiner's conjectural conclusions stated in the Office Action that the "fact that it (the composition of '221) adheres to the surface upon application indicates that it is a

pressure sensitive adhesive or that in the '942 patent the disclosed composition upon application to the tooth "requires exerting at least some pressure" provides factual evidence that the silicone resins disclosed in these patents are not pressure sensitive.

The rejection of Claim 14 under 35 U.S.C. 102(b) is traversed for basically the same reason as the traverse to the rejection of Claims 1 to 3, 6, 8 to 10 and 13, namely that the nonaqueous liquid tooth whitening composition used in the method of claim 14 contains a pressure sensitive silicone resin based adhesive which differs substantially both physically and chemically from the silicone composition disclosed in the '221 composition.

The rejection of Claim 14 under 35 U.S.C. 103(a) as being unpatentable over the '221 patent is also traversed.

The '221 patent does not teach the critical feature of Claim 14 namely the utilization in the tooth whitening method of a self adhering, elastomeric, tacky, pressure sensitive silicone resin component.

As the '221 patent teaches the use of silicone compounds as delivery systems for oral care additives including tooth whitening agents wherein the application of such systems dry to hard, rigid films chemically different from the systems presently claimed method, the '221 patent can only be held to teach away from the applicants claimed method. Such teaching away by the '221 patent from what the applicants have done "constitutes compelling evidence of nonobviousness", Cf. In re Hedges 228 USPQ 685 (Fed. Cir. 1986).

The objection to Claim 10 that the term "adhesion enhancing agent" is extremely broad is traversed.

The term "adhesion enhancing agent" is fully defined, with extensive examples, beginning at page 4, line 11 and continuing to page 5, line 8.

The Examiner's contention that each of the silicone fluid, gum or resin contribute to adhesion is irrelevant as applicants Claim 10 is dependent on Claim 1 which requires the presence of the inventive pressure sensitive silicone resin based adhesive component.

The rejection of Claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over the '221 patent in view of Sheraeff (U.S. 3,376,110) is traversed.

Sheraeff discloses the preparation of a solid stabilized hydrogen peroxide composition comprising hydrogen peroxide and a stabilizing amount of polyvinylpyrrolidone (PVP/H₂O₂). Sheraeff contains no teaching that PVP/H₂O₂ could be used as a whitening agent in pressure sensitive silicone resin based

adhesive tooth whitening systems. In the absence of applicants disclosure, there would be no reason why the skilled artisan of 35 U.S.C. 103(a) would be motivated by the '221 patent or Sheraeff to include PVP/H₂O₂ in pressure sensitive silicone resin based adhesive systems for tooth whitening application. As there is no reason or suggestion in the cited references for selecting PVP/H₂O₂ as a whitening agent for applicants pressure sensitive adhesive system, other than the knowledge learned from the applicants specification and Claims, even though it may have been "obvious to try" to use the PVP/H₂O₂ agent, as argued by the Examiner, "obvious to try" is not a proper standard for a rejection based nonobviousness Cf. In re Dow Chemical 5 USPQ 2d 1529 (Fed. Cir. 1988).

The rejection of Claims 1 and 10 to 13 under 35 U.S.C. 102(b) as being anticipated by Cilento et al (U.S. 5,059,189) is traversed.

Cilento et al discloses a multilayer pressure sensitive adhesive dressing consisting of an adhesive layer formulated from materials such as polyisobutylene which are suitable for use on human skin. The surface of the adhesive layer opposite the skin contacting surface is attached to a flexible backing layer.

In order for the polyisobutylene adhesive to adhere to moist body surfaces, water soluble swelling agents such as hydrocolloid gums must be added to the adhesive.

There is no teaching in Cilento et al of pressure sensitive adhesive composition which when topically applied to tooth surfaces forms an adherent layer which releases the peroxide compound to effect tooth whitening.

Cilento et al is not only not anticipatory of applicants invention under 35 U.S.C. 102(b) but the reference actually teaches away from applicants invention.

The basic component of the adhesive layer of the Cilento et al skin dressing material is a polybutylene which functions to provide adhesion to dry body surfaces. It is respectfully pointed out to the Examiner, that tooth surfaces are continuously bathed in saliva. Certainly the skilled artisan in the oral care art would not be motivated to try an adhesive system that is required to adhere to a dry surface skin to function in the moist oral cavity. The fact that polybutylene is nontoxic to skin surfaces is no teaching that it would be acceptable for use in the oral cavity or that the skilled artisan of 35 U.S.C. 103(a) would be motivated to try the Cilento et al polybutylene pressure sensitive adhesive in moist oral cavity applications.

The fact that the Cilento et al pressure sensitive adhesive requires a moisture absorbing water soluble or water swellable agent to permit compositions to adhere to moist body surfaces is a further teaching away of the anhydrous adhesive system claimed by applicants.

Applicants amended Claim 1 requires that the tooth whitening composition be a pressure sensitive silicone resin based adhesive containing a peroxide compound which peroxide compound when released from the adhesive layer will effect tooth whitening. Cilento et al discloses the addition of benzoyl peroxide to the polybutylene adhesive layer. Benzoyl peroxide is described by Cilento et al as an anti-acne agent. Although benzoyl peroxide is a peroxide compound there is no teaching in Cilento et al that benzoyl peroxide could or would be a peroxide compound which when released from the polyisobutylene adhesive layer would be effective in tooth whitening.

The rejection of Claims 1 and 6 under 35 U.S.C. 102(b) as anticipated by '472 (WO99/62472) is traversed.

Although the '472 patent teaches at the bottom of page 3 that nontoxic polymers "including natural or synthetic elastomers such as ---" silicones" may be used as the adhesive layer of the claimed whitening strip, no definition of the term "elastomer" is provided by '472. Reference to the American Heritage Dictionary (second edition) defines the term "elastomer" as "any of various polymers having the elastic properties of natural rubber". Simply put, there is no teaching in '472 of a pressure sensitive silicone resin based adhesive component that could be used in tooth whitening applications.

As already discussed with respect to the '942 and '221 references, the fact that the strip of the '472 patent is applied by contact to the teeth, such teaching does not unequivocally imply that because such contact may involve finger pressure, that the adhesive "must" be pressure sensitive, calling attention to the Examiner again, that the silicone adhesives of '942 and '221 patents form hard, rigid films thereby evidencing that the disclosed adhesive is not pressure sensitive. As '472 patent does not teach the use of pressure sensitive silicone resin based adhesives, '472 cannot be held to be anticipatory of presently amended Claim 1 under 35 U.S.C. 102(b).

The rejections of Claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over '472 patent in view of the '221 patent as well as Claims 4 and 5 over '472 in view of Sheraeff is traversed for the same reasons as previously stated, namely there is nothing in the references to suggest that a pressure sensitive

silicone resin based adhesive in combination with sodium percarbonate or PVP/H₂O₂ would function or be effective as a tooth whitening composition, and as already discussed these references by teaching the use of hard, rigid silicone films for delivery of oral care agents such as peroxide compounds actually teach away from the compositions of Claims 2-5.

The rejection of Claims 7 to 10 under 35 U.S.C. 103(a) as being unpatentable over '472 patent in view of Pfister et al (U.S. 5,232,702) is traversed.

Pfister et al discloses a transdermal drug delivery device comprising a backing substrate and a matrix comprising a silicone pressure sensitive adhesive atop the backing layer. The pressure sensitive adhesive of Pfister et al is comprised of a silicone fluid, a silicone resin and a cohesive strengthening agent, such as a nonionic surfactant and fatty acid esters. The cohesive strengthening agent functions to reduce the cold flow of the pressure sensitive adhesive. The cohesive strengthening agent does not function to enhance the adhesion of the adhesive to the skin. As stated in Pfister et al, the presence of the cohesive strengthening agent enables the adhesive to be retained intact on the skin of the patient wearing the bandage but does not compromise (that is does not reduce) the adhesion of the adhesive. There is no teaching that the cohesive strengthening agent enhances the adhesion of the adhesive.

In combining '472 patent and Pfister et al in rejection of the applicants claims, the Examiner has ignored the fact that the teachings of '472 patent contain no suggestion that the silicone resin based pressure sensitive adhesive could be used in the oral care application disclosed therein and further Pfister et al contains no teaching that silicone resin based pressure sensitive adhesives could be used in any application other than transdermal patches. Any connection between the two references is bridged only by the disclosure in applicants specification and Claims. This type of bridging is of course improper under the patent law and therefore the rejection under 35 U.S.C. 103(a) should be withdrawn.

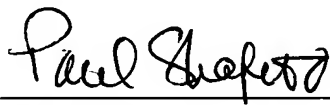
The rejection of Claim 13 under 35 U.S.C. 103(a) as being unpatentable over '472 patent is traversed. The '472 patent not only fails to specifically teach the amount of adhesive in the carrier layer on the whitening strip, the reference more importantly does not, as already discussed, teach that the carrier layer is composed of a silicone resin based pressure sensitive adhesive composition.

As in the case in all the rejections under 35 U.S.C. 103(a) set forth in the present Office Action, it is well settled that the obviousness of an invention cannot be established by combining the teachings of the

prior art absent, save a teaching, suggestion or incentive supporting the combination Cf. In re Fine 5 USPQ 2d 1596). Combining the teachings of '942 and '221 or '221 alone or in combination with Sheraeff, '472 and '221, '472 and Pfister et al, all suffer from the same absence of disclosure or motivation, namely there is no teaching or suggestion in any of these references that a pressure sensitive silicone resin based adhesive could be used as a delivery system for peroxide whitening of tooth enamel. It is only by using applicants own teachings and relying upon impermissible hindsight that one of ordinary skill in the oral care tooth whitening art would have been led to even contemplate combining the teachings of the cited references in the manner proposed by the Examiner. Therefore the rejections of applicants claims under 35 U.S.C. 103(a) should be withdrawn and the applicants claims as amended by passed to allowance.

Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul Shapiro", written over a horizontal line.

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PS/kml

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